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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,539	02/26/2002	Wenda Carlyle	PA872	9853

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER
FISHER, ABIGAIL L

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
05/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/085,539	CARLYLE ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7,9,11 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-7, 9, 11 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Request for Continued Examination filed on January 17 2008 and Amendments/Remarks filed on February 26 2008 is acknowledged. Claims 2-4, 8, 10 and 12-26 were/stand cancelled. Claim 5 was amended. Claims 1, 5-7, 9, 11 and 27 are pending.

Acknowledgment is made of Applicants previous election of polycaprolactone as the biocompatible polymer.

Withdrawn Rejections

The rejection of claims 1, 5-7, 9, 11, and 27 under 35 U.S.C. 103(a) as being unpatentable over Eury (US Patent 5,443,458) in view of W001/07066 (WO '066) is **withdrawn** in light of the declaration filed on February 26 2008.

The declaration filed on February 26 2008 under 37 CFR 1.131 is sufficient to overcome the WO 01/07066 reference.

The following represents all new grounds of rejections presented in this Office action.

Claim Interpretation

Claim 1 and the claims that depend from claim 1 contain the transitional language "consisting essentially of". For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or

claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *PPG Industries Inc. V Guardian Industries Corp.* 48 USPQ2d 1351 (Fed. Cir. 1998) and *In re De Lajarte* 337 F.2d 870, 143 USPQ 256 (CCPA 1964) **See MPEP 2111.03.**

The instant specification does not define the term "consisting essentially of" in a manner that would allow one skilled in the art to determine what basic and novel characteristics are being materially affected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as written is vague and indefinite. Line 2 of the claim indicates that **at least one** PPARγ agonist is present however line 4 of the claim indicates that the PPARγ agonist is rosiglitazone. Therefore, it is unclear if the coating comprises at least one PPARγ agonist or only rosiglitazone.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-7, 9, 11 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US Patent No. 5464650, cited on PTO Form 1449) in view of Su et al. (J. Clinical Investigation, 1999).

Applicant Claims

Applicant claims a site-specific drug delivery medical device consisting essentially of rosiglitazone and at least one biocompatible polymer. The biocompatible polymer is poycaprolactone. The device is a vascular or biliary stent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Berg et al. is directed to an intravascular stent. The invention allows for the sustained release of the drug to vascular tissue (column 2, lines 20-22). Many different active agents can be utilized. One particular example anti-inflammatory agents (column 5, lines 19-40). Example 3 is directed to a solution comprising only dexamethasone and polycaprolactone in acetone. This solution was applied to a stent to coat the stent.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Berg et al. does not specify that the therapeutic substance is rosiglitazone. However, this deficiency is cured by Su et al.

Su et al. indicates that PPARγ agonists reduce colonic inflammation. The results indicate that troglitazone or BRL 49653 (rosiglitazone) exhibit a highly significant anti-inflammatory effect (page 33, last paragraph).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Berg et al. and Su et al. and utilize rosiglitazone as the therapeutic substance. One of ordinary skill in the art would have been motivated to select

rosiglitazone as Berg et al indicates that anti-inflammatory are suitable therapeutic agents to be utilized in the stent coating and Su et al. indicates that rosiglitazone exhibits significant anti-inflammatory effect. Further more, the selection of a specific drug is considered prima facie obvious depending on the desired condition/symptoms to be treated.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-7, 9, 11 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 11383262. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a site-specific drug delivery medical device consisting essentially of rosiglitazone and at least one biocompatible polymer. The biocompatible polymer is poycaprolactone. The device is a vascular or biliary stent

Copending '262 claims a biodegradable polymer for coating an implantable medical device comprising a first monomer and optionally a second monomer wherein said first monomer comprises a modified caprolactone. Medical devices claimed include vascular stents. The polymer further comprises a drug.

The difference between the instant application and copending '262 is that the instant application claims a specific type of drug.

The relationship between the instant application and copending '262 is a genus-species relationship. Rosiglitazone is a particular type of drug. Therefore, both the instant application and copending '262 are directed to similar subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, 9, 11 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-18 of copending Application No. 11619122 in view of Berg et al. and in

further view of Su et al.. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a site-specific drug delivery medical device consisting essentially of rosiglitazone and at least one biocompatible polymer. The biocompatible polymer is poycaprolactone. The device is a vascular or biliary stent

Copending '122 claims a coating for an implantable medical device comprising a biocompatible amphiphilic polymer comprising a polyester and a polyether backbone. The monomers are selected from a group that includes caprolactone. The medical device as claimed includes vascular stents.

Copending '122 does not claim that the coating comprises rosiglitazone. However, this deficiency is cured by Berg et al. and Su.

Berg et al. is directed to intravascular stents. The inclusion of a polymer in contact with a drug on the stent allows for the drug to be retained on the stent and allows for control of the drug release (abstract). It is disclosed that stents are utilized to provide therapeutic substances to the vascular wall (column 1, line 58-59). Therapeutic substances that can be delivered include anti-inflammatory agents (column 5, line 28).

Su et al. indicates that PPARγ agonists reduce colonic inflammation. The results indicate that troglitazone or BRL 49653 (rosiglitazone) exhibit a highly significant anti-inflammatory effect (page 33, last paragraph).

It would have been obvious to one of ordinary skill in the art to combine Copending '122, Berg et al. and Su et al. and include a rosiglitazone in the coating of

Copending '122. One of ordinary skill in the art would have been motivated to include a drug because Copending '122 is directed to coatings for stents and Berg et al. indicates that stents are utilized to provide therapeutic substances to the vascular wall. One of ordinary skill in the art would have been motivated to select rosiglitazone as the therapeutic substance because Berg et al. indicates that therapeutic substance that can be delivered include anti-inflammatory agents and Su et al .indicates that rosiglitazone exhibits significant anti-inflammatory effects. Further more, the selection of a specify drug is considered prima facie obvious depending on t he desired condition/symptoms to be treated.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/

Primary Examiner
Art Unit 1616